

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration

Anti-Infective Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Anti-Infective Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on January 29, 2001, 8 a.m. to 6 p.m. and January 30, 2001, 8 a.m. to 4:30 p.m.

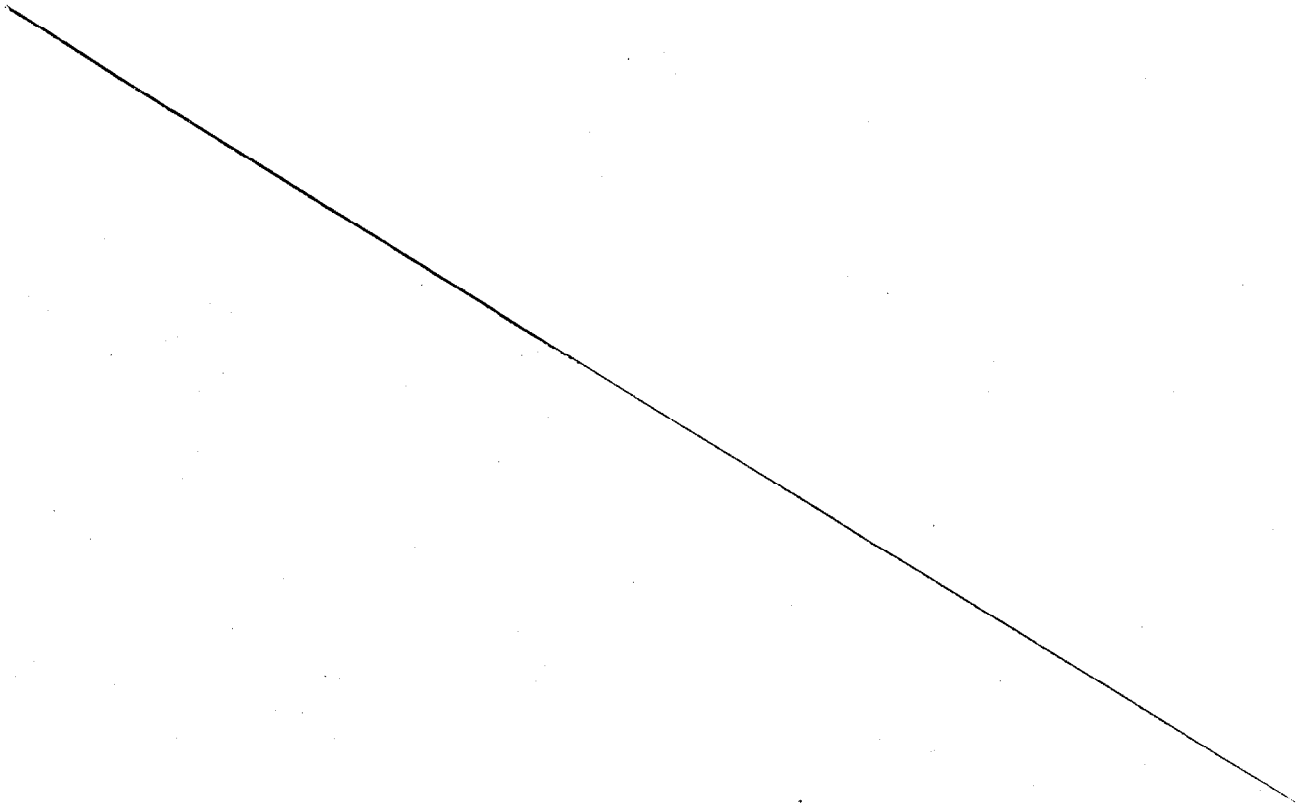
Location: Holiday Inn, The Ballrooms, Two Montgomery Ave., Gaithersburg, MD.

Contact Person: Thomas H. Perez, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-6758, e-mail: PerezT@cder.fda.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12530. Please call the Information Line for up-to-date information on this meeting.

Agenda: On January 29, 2001, the committee will consider the safety and efficacy of new drug application (NDA) 21-144, Ketek™ (telithromycin) tablets, Aventis Pharmaceuticals, Inc., for the treatment of community-acquired pneumonia, acute exacerbation of chronic bronchitis, acute sinusitis, and tonsillitis/pharyngitis. On January 30, 2001, the committee will consider the safety and efficacy of NDA 50-755, Augmentin ES™ (amoxicillin/clavulanate) 90 milligrams per

kilogram per day, SmithKline Beecham Pharmaceuticals, for the treatment of pediatric patients with acute otitis media due to penicillin resistant *Streptococcus pneumoniae*.


Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by January 22, 2001. Oral presentations from the public will be scheduled on January 29, 2001, between approximately 2 p.m. and 3 p.m., and on January 30, 2001, between approximately 2:45 p.m. to 3:45 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before January 22, 2001, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.



Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app.

2).

Dated: December 18, 2000.


Linda Suydam,
Senior Associate Commissioner.

[FR Doc. 00-????? Filed ??-??-00; 8:45 am]

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